

REMARKS

Claims 1-66 are pending in the application. Of these, claims 10, 16, 17, 23, 26-33, 37, 39 and 41-66 have been withdrawn from consideration under a restriction. Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are pending in the application and are rejected.

Restriction/Election

Applicants' election of Group I claims (claims 1-40) with traverse is acknowledged by the Examiner. Applicants' argument that any searches would be co-extensive was not accepted by the Examiner and the requirement was maintained to be proper and made final. Claims 41-46 are withdrawn from consideration as drawn to non-elected inventions and claims 10, 16, 17, 23, 26-33, 37 and 39 are withdrawn as being directed to non-elected species.

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 have been examined.

Objection to the Declaration

The declaration has been objected to because un-initialed changes were made to the address of Inventor Latouche.

A new declaration will be submitted.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. §112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Action admits that peptide "E495" is disclosed in the application but allegedly is not described on page 40 of the application.

In addressing Applicants' response to identification of the peptide sequence being supported by information in the Papanicolaou, *et al.* paper, the Examiner takes the position that Applicants are attempting to define the peptide with a post-filing

publication. Additionally, the Examiner notes that Papanicolaou discloses P495 peptide as NLVPMVATV, whereas Applicants indicated that the sequence of E495 is NLVMVATV.

Applicants first apologize for the transcriptional error in previously advising that E495 has sequence NLVMVATV. The sequence of E495 is NLVPMVATV.

Applicants respectfully disagree with the rejection.

It is Applicants' position that E495 is not only disclosed but also adequately described in the specification in Example 16 on page 40. It is well-established that claims are read in light of the specification. Example 16 identifies the protein as an amino acid segment from cytomegalovirus protein pp65, which is well-known. The peptide itself is identified as E465 which is known as an epitope of pp65. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. §112, first paragraph as lacking enablement such that one of skill in the art to which it pertains or is most nearly connected would not be enabled to make or use the invention.

Particularly, the Action alleges that the specification fails to show how to make the E495 peptide. Applicants respectfully disagree.

The Examiner takes the position that the only disclosure of the E495 peptide is on page 40 of the specification, where the text states that it is derived from CMV pp65 protein. The Examiner admits that the pp65 protein is known in the art, but that E495 cannot be made because it is not found in a search of Medline.

Additionally, the Action does not acknowledge the priority date of U.S. Provisional application 60/209,157 filed June 2, 2000 because it purportedly does not disclose the elected peptide species E495.

Applicants' guidance for making and using the invention is set forth in the specification and was presented under the presumption, as recognized by the Examiner, that the guidance is directed to one of skill in the art. It is well-established that protein chemists will use shorthand designations for peptides, particularly when a peptide is a segment of a known, sequenced and numbered full protein. Pp65 is "known in the art" as admitted by the examiner. A CMV pp65 derived protein named "E495" will instantly be recognized by one of skill in the art to be a segment of pp65 that starts with amino acid number 495, especially when consulting the literature described herein

The skilled practitioner will also look at the specification in its entirety and recognize that E495 is shorthand for the CMVpp65₄₉₅₋₅₀₃ peptide. This is recognized in part because other peptides that activated CTLs were nonamers (see Example 17 on page 41). However, the skilled practitioner is also aware of the knowledge available for E495 at the time of the filing of the application and could rely on the published sequence of E495.

A 1997 reference (Diamond, *et al.*) identifies a pp65₄₉₅₋₅₀₃ as a potential vaccine candidate. It is evident that this peptide is the same as the E495 used by Applicants. The peptide applicants have identified as E495 has consistently appeared in the literature as the only epitope of interest derived from the 495 region of pp65. It is Applicants' position that the artisan skilled generally in the field of immunology and familiar with antigen/vaccines would have no trouble immediately recognizing that E495 is only shorthand for the well-known pp65₄₉₅₋₅₀₃ antigen.

In summary, even if one relied on an outside reference to confirm the amino acid sequence of E495, there is sufficient disclosure in Applicants' specification to enable use of the invention. It is not undue experimentation to refer to an outside reference for the

sequence of a known compound. The Wands Factors are not applicable because the peptide is known, its sequence easily accessed, and its use and activity clearly demonstrated. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. §103

Claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40 are rejected under 35 U.S.C. 103(a) as unpatentable over Latouche, *et al.*, (2000) in view of Boeckh (1999). According to the Action, Latouche teaches an artificial antigen presenting cell comprising a human fibroblast expressing B7.1 and HLA A2.1 (which includes a human B-2 microglobulin) from recombinant viruses and present a T-cell epitope. The Examiner concludes that the limitations of the claims are met by the AAPC of the reference.

Applicants respectfully request removal of the Latouche, *et al.* reference as prior art. The reference names inventors Sadelain and Latouche as authors of a paper published in April, 2000. The present application takes priority from a provisional application filed in June of 2000, which is within the year of publication of the reference. An obviousness rejection, as here, based on a publication which could be applied under 35 U.S.C. 102(a) as indicated by the Action, can be overcome with a Katz Declaration. Applicants submit herewith a declaration under 37CFR 131. Accordingly, it is respectfully submitted that the Latouche, *et al.* reference is removed as prior art.

It is submitted that the Boeckh reference is not applicable as prior art alone and cannot be combined with the Latouche reference, which has been properly removed. Applicants respectfully request reconsideration and withdrawal of the rejection to claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40.

Supplemental Information Disclosure Statement

Applicants submit concurrently herewith a Supplemental Information Disclosure Statement for the Examiner's consideration, and respectfully request that the cited references be made of record. Copies of the publications are enclosed with this response.

CONCLUSION

Applicants believe that all formalities have been complied with and a complete response has been submitted. It is respectfully submitted that this application is now in condition for allowance with claims 1-9, 11-14, 18-22, 24, 25, 34-36, 38 and 40. Should any issues remain or should the Examiner believe that a telephone conference with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Date: November 24, 2004

By: Amy Leahy
Amy Leahy, Registration No. 47,739
Attorney for Applicants
EDWARDS & ANGELL, LLP
P.O. Box 55874
Boston, MA 02205
(203) 353-6817

Customer No.: 21,874